

REMARKS

Claims 33-38 and 42-45 were examined and rejected. The claims have been amended as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

Claims 33-37 and 42-44 were rejected under 35 U.S.C. 102(b) as being anticipated by Gordon et al. U.S. Pat. No. 5,458,609.

Claim 33 has been amended to specify that the device includes a flexible catheter which can be introduced into the body lumen through a first access penetration in the lumen wall and is adapted to be advanced along the length of the body lumen. Gordon et al. describes a method and device for the placement of sutures for the closure of wounds and for the purpose of approximating tissue. Thus, the Gordon et al. device 2 is designed to be positioned vertically within a puncture wound 14 so that tissue to be sutured lies on opposite sides of the device 2. There is no indication in the figures or the description that the device 2 is flexible and adapted to be advanced along the length of a body lumen. Further, specific features of the Gordon et al. device 2 indicate that the device 2 is not flexible and adapted for such use. For example, outer housing 32 is preferably made of injection molded plastic such as polycarbonate, pushrod 42 is constructed of stainless steel and elongate rigid shafts 50a and 50b are described as rigid (col. 11, lines 40-47). Also, the presence of catch mechanisms 16 on the device 2 for catching the needles 6 driven out of the guide tracks 10 indicates that the orientation of the catch mechanism 16 to the guide track 10 would be relatively constant, a feature which may not be the case if the device 2 were flexible and adapted for use as described. Therefore, Applicants believe **claim 33** and dependent **claims 34-37** are allowable in view of this rejection.

Similarly, **claim 42** has been amended to specify that the device includes a flexible catheter which can be introduced into the body lumen through a first access penetration in the lumen wall and is adapted to be advanced along the length of the body lumen. Therefore, Applicants believe that claim 42 has been differentiated from Gordon

et al. for the same reasons as above and that **claim 42** along with dependent **claims 43-44** are allowable in view of this rejection.

Claims 33-38 and 42-45 were rejected under 35 U.S.C. 102(b) as being anticipated by Voda U.S. Pat. No. 5,462,561.

Claim 33 has been amended as stated above and to specify that the means advancable is also retractable into the catheter after creating the second access penetration. Voda describes an apparatus for suturing a perforation in a side wall of a patient's blood vessel. The Voda device or carrier means 116 includes an elongated carrier shaft 118 and first and second laterally extendable arms 124 and 126. The carrier means 116 is described and illustrated in Figs. 25-28 to enter the perforation in the side wall so that the arms 124, 126 extend laterally within the blood vessel. The arms 124 and 126 carry suture points 108 which penetrate the side wall of the blood vessel so that the suture points 108 are located outside the side wall with the suture threads 106 running through the side wall into the blood vessel. Thus, the arms 124, 126 themselves do not penetrate the side wall. The suture points 108 are described to have a sharp point 110 which can be driven through the side wall and first and second anchor wings or barbs 112 and 114. The wings 112 and 114 spread apart from each other when tension is placed upon the suture thread 106 so as to anchor the suture point 108 and prevent the suture point 108 from being pulled back through the side wall of the blood vessel (col. 8, lines 54-58). Thus, the suture points 108 are not retractable into the Voda device after creating the penetration. And, such retractability would be contrary to the described functionality of the Voda device. For these reasons, Applicants believe **claim 33** and dependent **claims 34-38** are allowable in view of this rejection.

Similarly, **claim 42** has been amended as stated above and to specify that the penetrating element reciprocatably is mounted in the lumen of the guide tube so that the penetrating element can be retracted after creating the second access penetration. As stated above, the suture points 108 are not retractable into the Voda device after creating the penetration. And, such retractability would be contrary to the described functionality

of the Voda device. For these reasons, Applicants believe **claim 42** and dependent **claims 43-45** are allowable in view of this rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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APPENDIX A
VERSION WITH MARKINGS TO SHOW CHANGES MADE

33. (Twice Amended) A device for positioning a filament in a body lumen having lumen walls, said device comprising:

a flexible catheter which is adapted to [can] be introduced into the body lumen through a first access penetration in the lumen wall and advanced along the length of the body lumen; and

means advancable from the catheter for creating a second access penetration in the lumen wall and providing a filament path along the length of the body lumen between said first and second access penetrations, the means advancable also being retractable into the catheter after creating the second access penetration.

42. (Amended) A device for positioning a filament in a body lumen, said device comprising:

a flexible catheter which can be introduced through a first access penetration into the body lumen and advanced along the length of the body lumen, said catheter having a proximal end, a distal end, and a lumen therethrough;

a guide tube reciprocatably disposed in the lumen of the catheter so that the guide tube can be advanced from the distal end of the catheter, said guide tube having a proximal end, a distal end, and a lumen therethrough, wherein the distal end of the guide tube is deflectable; and

a penetrating element reciprocatably mounted in the lumen of the guide tube so that the penetrating element can be advanced from the distal end of the guide tube to penetrate a luminal wall in a direction determined by deflection of the distal end of the guide tube creating a second access penetration and providing a filament path along the

length of the body lumen between the first and second access penetrations, and so that the penetrating element can be retracted after creating the second access penetration.